

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIONPHARMA INC.,

Plaintiff,

v.

CORERX, INC.,

Defendant.

Case No. 21-cv-10656 (JGK)

**DEFENDANT CORERX, INC.'S MEMORANDUM OF LAW IN SUPPORT OF
EMERGERNCY MOTION TO STAY PRELIMINARY INJUNCTION PENDING
APPEAL AND TO SET SECURITY**

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PRELIMINARY STATEMENT

Following the Court’s resolution of the motion of Plaintiff Bionpharma Inc. (“Bionpharma”) for, and its corresponding entry of, on February 4, 2022, a preliminary injunction (ECF No. 79) (the “Preliminary Injunction” or simply “Injunction”) compelling Defendant CoreRx, Inc. (“CoreRx”) to produce and deliver to Bionpharma 18,459 bottles of a specific generic pharmaceutical product (the “Product”) by dates certain pursuant to the parties’ Master Manufacturing Supply Agreement (the “Agreement”), CoreRx brings this emergency motion seeking, on an expedited basis, the following: (1) a stay of the Preliminary Injunction pending the resolution of an appeal from this Court’s order and opinion awarding such relief (or at the very least, a stay until the Court of Appeals rules on the question of a stay); and (2) an order, pursuant to Federal Rule of Civil Procedure 65(c), requiring Bionpharma to post security to maintain the Injunction. This memorandum discusses these two requests in turn.¹

STATEMENT OF FACTS AND PROCEDURAL HISTORY

CoreRx respectfully refers the Court to the parties’ prior submissions and briefing on Bionpharma’s motion for the Preliminary Injunction, and the Court’s Opinion and Order granting such motion, for a complete recitation of the facts and procedural history pertinent to the instant motion.² In the interest of brevity, such facts are not repeated here.

¹ Consistent with the Order of this Court dated December 14, 2021 (ECF No. 21) and the parties’ past practices in this action, we submit both this memorandum of law under seal, given its inclusion of confidential damages estimates. We submit contemporaneously herewith a redacted versions for filing on the public docket, from which these figures, but nothing else, have been redacted.

² This Court’s Opinion and Order granting the motion for Preliminary Injunction (ECF No. 50), reported as *Bionpharma Inc. v. CoreRx, Inc.*, --- F. Supp. 3d ----, 2022 WL 246742 (S.D.N.Y. Jan. 27, 2022), is cited herein as “Opinion,” with page numbers corresponding to the pages of the Slip Opinion as filed on ECF. Meanwhile, “Mov.” refers to Bionpharma’s corrected brief in support of its preliminary injunction motion (ECF No. 28); “Opp.” refers to CoreRx’s brief in opposition thereto (ECF No. 35); and “Reply” refers to Bionpharma’s reply brief (ECF No. 40). Lastly, “Damani Decl.” refers to the declaration of CoreRx CEO Ajay Damani filed contemporaneously herewith.

LEGAL STANDARD

A district court has broad discretion to stay the enforcement of an injunction pending appeal. *See Fed. R. Civ. P.* 62(c); *Nken v. Holder*, 556 U.S. 418, 433 (2009); *see also Bristol-Myers Squibb Co. v. McNeil-P.P.C., Inc.*, 973 F.2d 1033, 1037 (2d Cir. 1992) (stay granted pending appeal); *In re Platinum-Beechwood Litig.*, No. 18-CV-6658-JSR, 2019 WL 4411886, at *2 (S.D.N.Y. Aug. 21, 2019) (same); *Plummer v. Quinn*, No. 07-6154-WHP, 2008 WL 383507, at *2 (S.D.N.Y. Feb. 12, 2008) (same). Rule 62(d) further provides that a court may “suspend, modify, restore, or grant an injunction on terms for bond or other terms that secure the opposing party’s rights.” *Fed. R. Civ. P.* 62(d).

A motion for a stay pending appeal “is a motion, not to [the court’s] inclination, but to its judgment; and its judgment is to be guided by sound legal principles.” *Nken*, 556 U.S. at 434 (citations omitted). In determining whether to issue a stay, courts consider the following four factors: (1) whether the movant has made a strong showing of likely success on the merits of its appeal; (2) whether the movant will suffer irreparable injury absent the requested stay; (3) whether a stay will injure the other party or parties in the proceeding; and (4) whether the public interest will be better served if a stay issues. *Id.* at 426, 434; *Barretta v. Wells Fargo Bank, N.A.*, 693 F. App’x 26, 27 (2d Cir. 2017); *In re World Trade Ctr. Disaster Site Litig.*, 503 F.3d 167, 170 (2d Cir. 2010). The first two factors are the “most critical.” *Nken*, 556 U.S. at 434.

Importantly, while this test resembles the test used to determine whether to issue a preliminary injunction in the first instance, the two tests are not identical. Whereas a preliminary injunction cannot issue unless all four prongs are satisfied, *see Winter v. Nat. Res. Defense Council*, 555 U.S. 7, 20 (2008); *see also Psihogios v. John Wiley & Sons, Inc.*, No. 11 Civ. 1414(JSR), 2011 WL 4634172, at *2 (S.D.N.Y. Oct. 4, 2011) (“the preliminary injunction

standard is a conjunctive test” that requires the movant to “satisfy all four elements … in order to establish his entitlement to the ‘drastic and extraordinary remedy’ of a preliminary injunction”), the test for a stay allows for more flexible balancing of the four factors. In other words, the “degree to which a factor must be present varies with the strength of the other factors,” meaning that “more of one [factor] excuses less of the other.” *In re World Trade Ctr.*, 503 F.3d at 170 (quoting *Thapa v. Gonzales*, 460 F.3d 323, 334 (2d Cir. 2006)). Therefore, unlike a preliminary injunction’s requirement that the movant make a strong showing on both of the first two prongs, on a stay motion the requisite “[p]robability of success [on the merits] is inversely proportional to the degree of irreparable injury [required]. A stay may be granted with either a high probability of success and some injury, or vice versa.” *N.Y. Times Co. v. Dep’t of Health & Human Servs.*, No. 20 Civ. 3063 (GWG), 2021 WL 235138, at *2 (S.D.N.Y. Jan. 25, 2021) (citation omitted); accord *Mohammed v. Reno*, 309 F.3d 95, 101 (2d Cir. 2002) (same); *Tecnimed SRL v. Kidz-Med, Inc.*, 763 F. Supp. 2d 395, 418 (S.D.N.Y. 2011) (“the necessary level or degree of possibility of success will vary according to the court’s assessment of the other stay factors”), *aff’d*, 462 F. App’x 31 (2d Cir. 2012); *see also generally* 16A FED. PRAC. & PROC. JURIS. § 3954 (2021) (“The analysis thus somewhat resembles the test applied in the district court when evaluating a request for a preliminary injunction, though … the two tests are not identical. [With respect to stay motions], … if the balance of harms tips heavily enough in the stay applicant’s favor then the showing of likelihood of success need not be as strong, and vice versa.”) (collecting cases).

Relatedly, the standard for assessing the first prong—likelihood of success on the merits—is more lenient in the context of a motion to stay a preliminary injunction than in the context of evaluating whether such an injunction is warranted in the first place. Despite being frequently stated in a formulation that suggests it requires a “strong showing” of likely success

on the merits, the stay-pending-appeal test actually allows for a stay to be granted “even if [the movant] demonstrates *something less than a likelihood of success on the merits* of its appeal.” *Sutherland v. Ernst & Young LLP*, 856 F. Supp. 2d 638, 640 (S.D.N.Y. 2012) (emphasis added). Rather, to obtain a stay, a movant is only required to show it has a “substantial possibility, although less than a likelihood, of success on appeal.” *LaRouche v. Kezer*, 20 F.3d 68, 72 (2d Cir. 1994); *see also Citigroup Global Mkts., Inc. v. VCG Special Opportunities Master Fund Ltd.*, 598 F.3d 30, 37 (2d Cir. 2010) (explaining that the Supreme Court’s decision in *Nken* “did not suggest that this factor requires a showing that the movant is ‘more likely than not’ to succeed on the merits” of its appeal); *Jock v. Sterling Jewelers, Inc.*, 738 F. Supp. 2d 445, 447 (S.D.N.Y. 2010) (although movants’ appeal rested on what the district court deemed “immaterial” distinctions with binding precedent, it recognized that “the Court of Appeals may disagree,” and “for that reason alone” found the first prong of the stay test had been satisfied). Similarly, it is enough for purposes of the first prong for a movant to “show ‘serious questions’”—though not necessarily any probability of ultimate success—“going to the merits of its appeal.” *Sutherland*, 856 F. Supp. 2d at 640 (quoting *Citigroup*, 598 F.3d at 36).

As set forth below, based on a balancing of the four factors, the Court should exercise its discretion here to stay the Preliminary Injunction pending CoreRx’s appeal.

ARGUMENT

I. THE COURT SHOULD STAY THE PRELIMINARY INJUNCTION PENDING APPEAL

A. CoreRx’s Appeal Will Present Serious Questions that the Second Circuit May Very Well Resolve in its Favor

CoreRx acknowledges that, in deciding Bionpharma’s Preliminary Injunction motion, this Court recently considered the initial merits of the parties’ positions and ruled in Bionpharma’s favor in this regard. (*See* Opinion 17-22.) However, as explained above, courts

apply this factor differently—to wit, more leniently—in connection with stay motions than they do in evaluating the propriety of a preliminary injunction to begin with. As such, the Court may rule in CoreRx’s favor on this factor here without needing to determine that its prior decision to award the Injunction was probably in error. Indeed, under the more flexible “substantial questions” or “substantial possibility” of success standard used in the stay motion context, a stay may be appropriate where the appeal “presents an issue of first impression” *even if the district court “remains confident in the soundness of [its] reasons” for awarding the Injunction in the first place.* *Jock*, 738 F. Supp. 2d at 447 (emphasis added) (granting stay pending appeal that presented novel question for appellate court’s consideration). That is because, despite such confidence, “the Court of Appeals may [nevertheless] disagree” with its reasoning. *Id.*

As this Court acknowledged, even if tacitly, in its opinion granting Bionpharma the Preliminary Injunction, the issue of whether a contract, the performance of which possibly entails patent infringement, is preempted by the federal patent laws is one that has yet to be addressed by the Second Circuit (Opinion 18 (referencing dearth of directly relevant case law)), and given the ample case law tending to support CoreRx’s position on this front, there is at least a substantial question as to whether the Court of Appeals will resolve this important issue in CoreRx’s favor, thereby requiring vacation of the Injunction and dismissal of this entire action.

1. The Agreement is void as preempted by federal patent law.

There is a strong probability that the Second Circuit will reach a decision at odds with this Court’s conclusion that the Agreement is not preempted by the federal patent laws. (Opinion 18-20.) Ample case law—indeed, the weight of authority—supports CoreRx’s position that, by requiring CoreRx to violate the patent rights of third-party Azurity Pharmaceuticals, Inc. (“Azurity”), which manufacturers the brand name version of Bionpharma’s generic Product, the Agreement is preempted by the patent laws and therefore unenforceable.

As CoreRx explained in its opposition papers on the Preliminary Injunction motion (*see Opp.* 8-9), contracts that frustrate the purposes of the federal patent laws are preempted and without force, as the Supreme Court (among other courts) has recognized on a number of occasions, including in the seminal case of *Lear v. Adkins*, 395 U.S. 653, 670-71 (1969). *See also Brulotte v. Thys Co.*, 379 U.S. 29, 31-32 (1964); *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 256 (1945); *cf. Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979). In *Lear*, the Court explained that the federal patent laws are designed to, among other things, ensure that “all ideas in general circulation be dedicated to the common good unless they are protected by a valid patent,” and that the concerns of patent law outweigh the concerns of contract law. *Lear*, 395 U.S. at 668-71. Therefore, it held that agreements that violate or undermine federal patent law or policy—such as, in that case, a licensing agreement in which a licensee covenants not to challenge the validity of the licensed patent—are void. *Id.*

CoreRx respectfully submits that this Court missed the import of *Lear* in issuing its ruling on the Preliminary Injunction motion. The Court held that *Lear* “does not support CoreRx’s argument that ‘contracts that frustrate the purposes of the federal patent system are preempted and without force’” (Opinion 18 (quoting Opp. 8)), and pointed out that the contract provision invalidated in *Lear* was one that sought to *prevent* patentees from contesting patent validity, and thus that the Court’s decision was one that generally advocated in favor of challenging patents (*id.* at 19-20). But this misses the mark. Despite arising in a factual scenario where the contract provision at issue was one that sought to preclude parties from challenging the other contracting party’s patents—thus implicating the federal patent law’s goal of ensuring ideas that do not meet the standards for patentability be in the public domain (*see id.* at 19)—the general *principle* of that holding remains to be that contracts that undermine the patent law’s policies are preempted,

see Lear, 395 U.S. at 673 (“The *decisive question is whether overriding federal policies be significantly frustrated* if licensees could be required to continue to pay royalties during the time they are challenging patent validity in the courts . . .”) (emphasis added). That remains true even where, as here, the contractual provisions in question seek to frustrate the *countervailing* goal of the patent laws: encouraging and promoting innovation by granting patentees exclusive rights to their inventions for a 20-year term, and prohibiting infringement by others until that period has lapsed. (See Opp. 9-10 (citing, *inter alia*, *Aronson*, 440 U.S. at 262).)

In addition, this Court apparently read *Lear* to be distinguishable on the basis that the Court in that case addressed only the validity of the licensee estoppel doctrine, a common-law contract doctrine in cases involving contracts related to intellectual property rights—but not an actual contract, as here—vis-à-vis the federal patent laws. (Opinion 18.) Such a conclusion will not likely stand on appeal, as it ignores the Second Circuit case law that CoreRx cited construing *Lear* as requiring courts to balance public interests served by the federal patent laws against the often competing interests of contract law and “even [against] explicit contractual provisions . . . that would undermine public interest.” (Opp. 9 (quoting *Idaho Potato Comm’n v. M&M Produce Farm & Sales*, 335 F.3d 130, 137 (2d Cir. 2003)); accord *Rates Tech., Inc. v. Speakeasy, Inc.*, 685 F.3d 163, 167 (2d Cir. 2012).)

Relatedly, while the Court criticized CoreRx for having cited no case squarely supporting its position on the Agreement’s preemption (*see* Opinion 18), the same could be said for the position taken by Bionpharma and adopted by the Court; there was not a single case cited in the Court’s opinion or in Bionpharma’s submissions that addressed a fact pattern like this and ruled against preemption, either. As noted above, the dearth of factually analogous cases addressing the validity of such a contract, or the propriety of a court order compelling performance thereof,

means that CoreRx’s appeal will present an issue of first impression to the Second Circuit, which militates in favor of granting a stay pending appeal. (*See supra* Sec. I(A).) Moreover, CoreRx respectfully submits that this criticism rings hollow given that CoreRx *did* cite a number of in-circuit cases in which courts have found a contract trumped by patent law, and thus refused to honor the contract’s terms (*see* Opp. 9 (citing, *inter alia*, *Rates Tech.*, 685 F.3d at 172, *Alexsam, Inc. v. Mastercard Int’l Inc.*, No. 15-CV-2799 (ILG) (SMG), 2018 WL 7063137, at *5-7 (E.D.N.Y. Oct. 16, 2018)), and *Canon Inc. v. Tesseron Ltd.*, 115 F. Supp. 3d 391, 396 (S.D.N.Y. 2015)))—which the Court engaged in absolutely no discussion of, instead making no mention of any of these cases (or indeed citing a single case in this portion of its opinion other than *Lear* itself). The above precedent alone suggests that the Second Circuit may resolve the issue here in CoreRx’s favor—especially given that neither Bionpharma in its briefing or oral argument, nor the Court in its Opinion and Order, cited a single such case going the other way.

Finally, CoreRx submits that there is at least a reasonable possibility that the Court of Appeals reverses this Court’s decision on the preemption issue given that the ruling contravenes the patent law’s critical policy goal of encouraging innovation by granting to patentees an exclusive license to their patents for a 20-year term, *see* 35 U.S.C. §§ 154(a)(1)-(2); *see also id.* § 271(a); *Aronson*, 440 U.S. at 262, and by legally affording all patents the presumption of validity unless and until proven otherwise, 35 U.S.C. § 282; *see also Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95 (2011) (holding invalidity defense must be “proved by clear and convincing evidence”). While this Court found CoreRx’s preemption argument “unpersuasive” because “[n]o court has yet held that Bionpharma’s Product violates any federal patents” (Opinion 18), that holding simply ignores that Azurity’s patents are entitled to the presumption of validity under the statute, as highlighted in CoreRx’s prior briefing (*see* Opp. 10).

Moreover, this Court appeared to conclude that CoreRx will have difficulties showing infringement based on the ruling in Bionpharma’s favor in the *Silvergate* case. (Opinion 18.) But that case involved an entirely different patent, and different product variant, than those Azurity is raising at present based on this Product. *See Silvergate Pharms., Inc. v. Bionpharma Inc.*, No. 18-cv-1962, 2021 WL 1751148, at *1 (D. Del. Apr. 29, 2021); *see also* Opp. 11. Similarly, the fact that the court in Delaware denied Azurity’s request for a preliminary injunction enjoining Bionpharma from selling the Product in November of 2021 is not indicative of Bionpharma’s likely success on the merits here (*cf.* Opinion 18), given the vastly different standards applicable to a preliminary injunction motion and to a merits determination of a patent’s validity, *see Azurity Pharms., Inc. v. Bionpharma Inc.*, No. 21-cv-01286-LPS, ECF No. 87 (D. Del. Nov. 10, 2021).

In sum, “[a]bsent definitive appellate guidance, a court no matter how confident that its decision is correct must recognize that it is operating in an area [of] uncertainty.” *Hayes v. City Univ. of N.Y.*, 503 F. Supp. 946, 963 (S.D.N.Y. 1980). Due to the nature of this case’s fact pattern and the lack of any directly relevant precedent, there is a serious possibility that CoreRx prevails on appeal in having the Injunction invalidated.

2. The Agreement is void for illegality under New York law.

There is also a real possibility that the Second Circuit will conclude that the Agreement is unenforceable under New York law on grounds of illegality, given it effectively mandates violation of the patent laws.

This Court summarily rejected CoreRx’s argument that the Agreement is void under New York’s longstanding rule against unlawful contracts (*see* Opp. 12) on only the ground that “no court has yet held that CoreRx’s provision of the Product violates” Azurity’s patents (Opinion 20). It thereby implicitly accepted the notion that a violation of the patent laws, if demonstrated,

would constitute sufficient illegality to void the Agreement, despite the fact that, as Bionpharma attempted to argue, such a violation is only *malum prohibitum* and not *malum in se* (Reply 3)—and correctly so, in light of the authorities CoreRx cited supporting the view that New York law will not give effect to contractual provisions that require a party to engage in similar such form of unlawful conduct (Opp. 12 (citing *Vill. Taxi Corp. v. Beltre*, 91 A.D.3d 92, 93, 99-101 (2d Dep’t 2011), *24/7 Records, Inc. v. Sony Music Entm’t, Inc.*, No. 03 Civ. 3204(MGC), 2004 WL 2093132, at *5 (S.D.N.Y. Sept. 20, 2004), *Anabas Export Ltd. v. Alper Indus.*, 603 F. Supp. 1275, 1276-78 (S.D.N.Y. 1985), and 7 WILLISTON ON CONTRACTS § 16:14 (2021))).

Rather, as noted, the Court found CoreRx unlikely to prevail in arguing that the Agreement is void for illegality only because of the fact that no Court has yet to finally adjudicate whether CoreRx’s manufacture and supply of the Product pursuant to the Agreement, and/or Bionpharma’s subsequent sale thereof, infringes Azurity’s patents. (Opinion 18.) Here again, there is a serious question as to whether the Second Circuit will agree, given that, under the patent law, a patent is presumed valid until proven otherwise (*see supra* Sec. I(A)(1))—which has yet to happen.³

3. There is a substantial possibility that the Court of Appeals vacates the Preliminary Injunction by finding Bionpharma’s claimed reputational damages do not suffice to show irreparable harm.

Finally with respect to the first, success-on-the-merits prong, regardless of whether the Second Circuit agrees or not with CoreRx’s arguments as to the enforceability of the parties’ Agreement, and thus CoreRx’s ultimate likelihood of successfully overcoming Bionpharma’s breach-of-contract claims, it will be compelled to rule in CoreRx’s favor on appeal if it finds

³ CoreRx does not contend that the Agreement is illegal should Bionpharma succeed in proving the invalidity of the relevant Azurity patents in the Delaware litigation, and has always taken the position that should that come to pass, it will resume its obligations under the Agreement to produce and supply the Product to Biopharma; it maintains that the Agreement is illegal and thus void only until that happens. (*See* Damani Decl. ¶ 12, 14.)

Bionpharma “fail[ed] to demonstrate … that [it] would suffer irreparable harm absent an injunction.” *Faiveley Transp. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 119 (2d Cir. 2009); *see also Winter*, 555 U.S. at 20-22.

As the Court recognized in its Opinion awarding the Injunction here, irreparable harm is “the single most important prerequisite for the issuance of a preliminary injunction.” (Opinion 13 (quoting *Reuters Ltd. v. United Press Int'l, Inc.*, 903 F.2d 904, 907 (2d Cir. 1990)).) As such, even “upon a showing of likelihood of success on the merits,” a “[movant] must make an *independent* showing of irreparable injury” to obtain a preliminary injunction. *Goat Fashion Ltd. v. 1661, Inc.*, No. 19 Civ. 11045 (PAE), 2020 WL 5758917, at *4 (S.D.N.Y. Sept. 28, 2020) (emphasis added). In making that showing, the movant must identify “evidence” demonstrating that “absent a preliminary injunction [it] will suffer an injury that is neither remote nor speculative, but actual and imminent.” *Faiveley*, 559 F.3d at 118, 120 (citation omitted). And that evidence must show that “irreparable injury is likely in the absence of an injunction”—“not just a possibility.” *Winter*, 555 U.S. at 21-22. As the Supreme Court has explained, ordering injunctive relief based on the “mere *possibility* of irreparable harm is inconstant with [the well-settled] characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the [movant] is entitled to such relief.” *Id.* at 22 (emphasis added).

Contrary to what this Court previously concluded, CoreRx believes that the Court of Appeals is likely, based on the body of relevant precedent, to find that Bionpharma failed to make such a showing here. The overwhelming weight of precedential case law in this Circuit shows that courts will only find the requisite irreparable harm to exist by virtue of purported or actual reputational damages, as Bionpharma asserted here, “[where] the very viability of the

[movant]’s business” is at risk by virtue of the other party’s conduct. (Opp. 18 (quoting *Tom Doherty Assocs, Inc. v. Saban Entm’t, Inc.*, 60 F.3d 27, 38 (2d Cir. 1995)).) Indeed, this Court criticized CoreRx’s “attempts” to distinguish this case from the in-circuit cases like *Reuters, Rex Med. L.P. v. Angiotech Pharmas. (US), Inc.*, 754 F. Supp. 2d 616 (S.D.N.Y. 2010), and *John B. Hull v. Waterbury Petroleum Prods, Inc.*, 588 F.2d 24 (2d Cir. 1978), in which the requisite irreparable harm was found by virtue of a reputational damage to the movant, as “unavailing” (Opinion 15), yet it does so while ignoring the central, key distinguishing fact in each of those cases: that the defendant’s breach was likely to result in an inability to supply the *only product in the movant’s line of business*, and thus threatened the entire future viability of the company (see Opp. 16-18).

That is not the case here, as CoreRx has previously demonstrated. In fact, filings that Bionpharma has made in this action following the Court’s decision on the Preliminary Injunction motion openly acknowledge that CoreRx itself produces other products for Bionpharma to sell to its retailer-customers. (See ECF No. 73 at 2-3 (“the consequences (if any) of a delay in delivery of other products that CoreRx manufactures for Bionpharma are not an issue before the Court ...”); see also Damani Decl. ¶ 14.) This is *not* a case where the Product at issue constitutes 90% or more of Bionpharma’s entire business, as in *Reuters* and *Rex Med.*, or represents its only line of merchandise as in *John B. Hull*. (See Opp. 16-17; cf. Opinion 14-15.)

In addition, this Court rejected CoreRx’s argument that Bionpharma’s claims of irreparable reputational injury are conclusory because “Bionpharma has produced reliable affidavits swearing to its claimed harmed.” (Opinion 16.) CoreRx has good reason to believe the Court of Appeals will disagree. Conclusory statements in affidavits are still conclusory. To satisfy the irreparable harm element, the party seeking an injunction may not rely on mere

“speculative arguments” but must instead introduce “evidence of actual and imminent injury,” *Saint Laurie Ltd. v. Yves Saint Laurent Am., Inc.*, No. 13-cv-6857-DAB, 2014 WL 12772088, at *6 (S.D.N.Y. Sept. 30, 2014), showing “*how* [that party’s] reputation … is being damaged, and *how* [preliminary injunctive relief] would work to restore its reputation,” *Home It, Inc. v. Wupin Wen*, No. 19-cv-7070-MKB-VMS, 2019 WL 7168370, at *2 (E.D.N.Y. Dec. 23, 2019) (emphasis added); *see also Reuters*, 903 F.2d at 108 (summarizing the evidence movant presented, including deposition testimony and results of a survey of over thirty of its customers, that illustrated the actual of customer goodwill that would befall movant absent the entry of a preliminary injunction).⁴ CoreRx firmly believes that the Second Circuit will find Bionpharma’s conclusory affidavits, which are unmoored to a shred of factual substantiation or elaboration as to how or why such harm would be suffered, insufficient to satisfy this exacting standard. *See, e.g., Viamedia, Inc. v. WideOpenWest Fin., LLC*, No. 20 Civ. 4064, 2020 WL 8991776, at *1 (S.D.N.Y. May 27, 2020) (finding claims of “irreparable harm to [movant’s] reputation” in declaration of its Chief Revenue Officer to be “entirely conclusory, and unsupported by any factual allegations” and therefore insufficient to support finding of irreparable harm); *In re Document Techs. Litig.*, 275 F. Supp. 3d 454, 469 (S.D.N.Y. 2017) (“[DTI] has offer[ed] only conclusory statements from its Chief Integration Officer that the company saw ‘harm to [its] good will’ because of the Individual Defendants’ ‘abrupt’ departure … It is precisely this type of unsubstantiated testimony, disconnected from proof that any customers have actually ceased doing business with DTI or testimony from any clients that they think less of the company, that New York courts have held is insufficient to show actual or imminent harm to a plaintiff’s

⁴ The fact that reputational injury, once shown, can be difficult to value (*see* Opinion 14-15) does not excuse Bionpharma from producing evidence showing a concrete and imminent reputational injury in the first place. *See Saint Laurie*, 2014 WL 12772088, at *6.

‘goodwill.’’); *RegenLab USA LLC v. Estar Techs. Ltd.*, No. 16-cv-08771 (ALC), 2017 WL 3535008, at * (S.D.N.Y. Aug. 17, 2017) (“the Court agrees … that [executive officer]’s declaration is entirely too conclusory to support a finding that [company] will be irreparably harmed” absent its requested injunction); *Naden v. Numerex Corp.*, 593 F. Supp. 2d 675, 681 (S.D.N.Y. 2009) (“[It] was plaintiffs’ burden to demonstrate clearly the existence of an actual and imminent threat of irreparable injury. The vagueness and conclusory nature of the affidavits and testimony of the three individual plaintiffs leaves this Court unpersuaded.”)

CoreRx also believes a substantial question exists as to whether the Second Circuit will agree with this Court’s analysis of the Agreement’s limitation-of-liability clause in Section 13.5, which precludes Bionpharma from recovery any “consequential damages,” including “economic losses or lost profits,” flowing from a breach by CoreRx. (*See* Opinion 15-16.) It is simply implausible that, if Bionpharma had any fear that a breach by CoreRx would result in reputational harm that was not compensable through an award of money damages, it would have contracted away any ability to recover for such harm.

In sum, any reputational harm that Bionpharma may be caused to suffer as a result of CoreRx’s purported breach fail as a matter of law to establish the requisite irreparable harm, and thus fail to establish Bionpharma’s entitlement to the extraordinary remedy of a preliminary injunction before it has proved its case. Bionpharma’s theory, adopted by this Court, is unlikely to withstand appellate review, which only further militates in favor of staying the Injunction.

B. CoreRx Will Suffer Irreparable Harm Absent a Stay

Unlike Bionpharma, CoreRx actually *will* suffer irreparable harm if the Preliminary Injunction is enforced while CoreRx’s appeal is pending—harm that will far outweigh any monetary losses sustained by Bionpharma during that period.

As CoreRx argued in its brief in opposition to the Preliminary Injunction motion, the Injunction, by compelling CoreRx to continue supplying the Product to Bionpharma in contravention of both the federal patent laws and of patents validly held by third-party Azurity, will expose CoreRx to liability for damages to Azurity in the eight or nine figures—enough to wipe CoreRx, which lacks assets sufficient to satisfy such a judgment, completely out of business. (*See Opp.* 20.) This would, in turn, force CoreRx’s hand in laying off over 200 workers currently employed in its factories. (Damani Decl. ¶ 18.)

The Court rejected CoreRx’s theory of harm on the following two bases: (1) the ostensible “implausibility” that “Azurity, CoreRx’s sister company, would risk bankrupting CoreRx”; and (2) Bionpharma’s promise to “indemnify CoreRx for any costs associated with patent infringement” claims. (Opinion 23-24; *see also id.* at 6.) Both bases have since, however, been called into question in further filings in this matter. Specifically, Azurity moved to intervene in this action on February 2, 2022, and in its motion papers affirmatively represented to the Court that it *does* intend to re-open its infringement actions against CoreRx in the event CoreRx continues supplying Product to Bionpharma. (*See ECF No.* 67, at 5-6 (“Azurity stands ready to enforce its ... patent rights: contrary to Bionpharma’s false arguments to the Court that Azurity and CoreRx are “affiliates” or “sister companies,” and that Azurity is therefore unlikely to sue CoreRx, Azurity will be compelled by its interest to protect its product to renew litigation against CoreRx ...”); *see also* Damani Decl. ¶ 11.) Similarly, in its submissions post-dating this Court’s issuance of its decision to award the Preliminary Injunction, Bionpharma has backtracked on its earlier promises to indemnify CoreRx, now taking the position that it has *no* obligations, and *no* intent, to provide *any* amount of indemnity. (*See ECF No.* 73, at 3-4; Damani Decl. ¶ 17.) In light of these developments, there is plainly reason for this Court to

revisit—and, ultimately, reverse—its prior determination that the Preliminary Injunction will not seriously damage CoreRx.

C. Bionpharma Will Suffer No Material Harm Should the Court Stay Enforcement of the Preliminary Injunction

On the other side of the ledger, Bionpharma will not suffer irreparable injury if a stay is granted but, at most, only injury compensable through a future award of money damages. For the same reasons identified in Section I(A)(3), *supra*, Bionpharma’s unsupported fear of reputational injury is insufficient to demonstrate the requisite irreparable harm as a matter of law, and any harm suffered by Bionpharma would be negligible compared to the serious, concrete harms that CoreRx (and over 200 blue-collar American families) will face as a result of the Preliminary Injunction.

D. The Public Interest Favors a Stay

Lastly, public policy interests also support a stay. It is widely accepted that there is an important and substantial public interest in promoting and rewarding innovation, which was one of Congress’s main objectives in enacting the federal patent laws. *See Canon Inc. v. GCC Int’l Ltd.*, 450 F. Supp. 2d 243, 257 (S.D.N.Y. 2006) (“There is a strong public interest in ensuring that valid patents are enforced. Such enforcement encourages and promotes useful inventions.”); *Endo Pharms. Inc. v. Amneal Pharms., LLC*, Nos. 12 Civ. 8115 (TPG), 12 Civ. 8060 (TPG), 12 Civ. 8317 (TPG), 12 Civ. 8985 (TPG), 13 Civ. 435 (TPG), 13 Civ. 436 (TPG), 13 Civ. 3288 (TPG), 13 Civ. 4343 (TPG), 13 Civ. 8597 (TPG), 2016 WL 1732751, at *7 (S.D.N.Y. Apr. 29, 2016) (“[T]he Federal Circuit ‘has long acknowledged the importance of the patent system in encouraging innovation. Indeed, the ‘encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.’”’) (quoting *SanofiSynthelabo v. Apotex, Inc.*, 470 F.3d 1363, 1383 (Fed. Cir. 2006)). Granting a stay

pending appeal under the unique circumstances of this case would promote the patent law's Congressionally-mandated policy of stimulating and encouraging invention by respecting—and presuming the validity of—inventors' existing patents unless and until a challenger proves their invalidity.⁵

In addition, as noted above, without the stay, CoreRx will face exposure to Azurity in the many millions of dollars—which would lead the company to file for bankruptcy. This would, in turn, force CoreRx to lay off over 200 factory workers who work in its Florida plant, causing immense hardship to over 200 blue-collar families that rely on CoreRx paychecks as their primary, if not their only, means of subsistence. (Damani Decl. ¶ 18.)

The Court found otherwise in its decision to award the Preliminary Injunction, and instead found that the public interest factor weighed in Bionpharma's favor, given that the Product is a generic version of the brand name Epaned® drug, and thus much cheaper for the “families with sick children,” the target market for Bionpharma’s product. (Opinion 24.) The Court’s decision appears to be based on nothing more than emotional appeal. As CoreRx ably demonstrated in its Opposition, the price difference between these two drugs as borne by the actual end-customer is indeed very slight (Opp. 22-23), and the Court provides nothing whatsoever to support its vague assertion that “for families with sick children, even [such a] small increase can make a significant difference” (Opinion 24). Moreover, while the Court was persuaded by the notion that certain insurers “cover only Bionpharma’s [generic] product” (*id.*), that is only so because that Product *is available in the market*; were it not, it can be assumed that

⁵ In addition, the public has an interest judicial economy and the preservation of judicial resources, which typically are preserved by staying a case pending appeal. See, e.g., *Estate of Heiser v. Deutsche Bank Tr. Co.*, No. 11-1608-AJN MHD, 2012 WL 2865485, at *5 (S.D.N.Y. July 10, 2012); *Satcom Int'l Grp. plc v. Orbcomm Int'l Partners, L.P.*, 55 F. Supp. 2d 231, 236-37 (S.D.N.Y. 1999); *In re United Health Care Org.*, 210 B.R. 228, 234 (S.D.N.Y. 1997); *Sutherland*, 856 F. Supp. 2d at 644.

the same insurers *would* provide coverage for Epaned® (*see* Mov. 16-18). Finally, as CoreRx pointed out in opposing the motion for a Preliminary Injunction, the exclusivity period is soon to open up allowing entry of competing generics, and Azurity, for one, has already stated in court proceedings in the District of Delaware that it is planning to put its own authorized generic on the market to compete with Bionpharma’s Product. (*See* Opp. 23 & n.4 (citations omitted).)

E. In the Alternative, a Brief Stay Should Issue to Allow the Court of Appeals to Consider the Stay Issue

In addition to its Notice of Appeal, CoreRx will timely file a request for an expedited appeal pursuant to Rule 62. In the alternative to its request for a stay of the Injunction pending the resolution of its entire appeal, CoreRX requests, at a minimum, a brief stay so that the Court of Appeals may consider its stay request. As the Second Circuit has recognized, brief, interim stays of this nature are “frequently issued when a district court denies an open-ended stay pending appeal. They give the appellate court an opportunity to decide whether an additional stay and an expedited appeal should be granted.” *Rodriguez ex rel. Rodriguez v. DeBuono*, 175 F.3d 227, 235-36 (2d Cir. 1999); *see also Diorinou v. Mezitis*, 237 F.3d 133, 138 (2d Cir. 2001) (district court “helpfully stayed its order … to permit Mezitis to seek a stay pending appeal from this Court”); *SEC v. Brennan*, 230 F.3d 65, 69-70 (2d Cir. 2000) (“The District Court denied the stay, but granted an interim stay … to allow [appellant] to seek relief in this Court.”); *Arctic Ocean Int’l, Ltd. v. High Seas Shipping, Ltd.*, No. 06 Civ. 1056(LAP), 2009 WL 5103283, at *2 (S.D.N.Y. Dec. 28, 2009) (granting interim stay pending resolution of application for stay submitted to the Second Circuit); *Centauri Shipping Ltd. v. W. Bulk Carriers KS*, 528 F. Supp. 2d 186, 196 (S.D.N.Y. 2007) (same); *LNC Invs., Inc. v. Rep. of Nicaragua*, No. 96CIV.6360(JFK), 2000 WL 729216, at *2 (S.D.N.Y. June 6, 2000) (same). If this Court is not inclined to stay enforcement of the Preliminary Injunction until CoreRx’s full appeal is decided,

then CoreRx respectfully asks it grant a short stay until the Court of Appeals rules on the issue of a stay and expedited appeal.

II. BIONPHARMA SHOULD BE REQUIRED TO POST SECURITY TO MAINTAIN THE INJUNCTION

Rule 65 is clear: “The court may issue a preliminary injunction … *only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.*” Fed. R. Civ. P. 65(c) (emphasis added); *see also* Fed. R. Civ. P. 62(d) (“While an appeal is pending from an interlocutory order or final judgment that grants, continues, modifies, refuses, dissolves, or refuses to dissolve or modify an injunction, the court may suspend, modify, restore, or grant an injunction on terms for bond or other terms that secure the opposing party’s rights.”). As the Court of Appeals has explained, “the text of Rule 65(c) suggests that ‘[t]he draftsmen must have intended that when … damages were incurred’ by the party opposing the preliminary injunction, the other party “‘would normally be required to pay [any] damages’” as a result of being subject to an injunction later found to be unmerited. *Nokia Corp. v. InterDigital, Inc.*, 645 F.3d 553, 558 (2d Cir. 2011) (quoting *Coyne-Delany Co., Inc. v. Capital Dev. Bd. of Ill.*, 717 F.2d 385, 392 (7th Cir. 1983)); *see also*, e.g., *Veeco Instruments Inc. v. SGL Carbon, LLC*, No. 17-CV-2217 (PKC), 2017 WL 8676438, at *1, *9 (E.D.N.Y. Dec. 26, 2017) (denying stay of preliminary injunction but requiring party who moved for it to post \$7.5 million bond); *WPIX, Inc. v. ivi, Inc.*, No. 10-cv-7415, 2011 WL 1533175, at *4 (S.D.N.Y. Apr. 19, 2011) (court denied motion to stay injunction pending appeal, but amended injunction to require security be posted).

While courts may excuse the posting of a bond in certain cases, such cases are rare—indeed, “so rare that the requirement is almost mandatory.” *Frank’s GMC Truck Ctr., Inc. v.*

Gen. Motors Corp., 847 F.2d 100, 103 (3d Cir. 1988); *see also Habitat Ed. Ctr. v. United States Forest Serv.*, 607 F.3d 453, 457 (7th Cir. 2010) (nonprofits not exempt from bond requirement); *Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 421 (4th Cir. 1999) (failure to require bond is reversible error); *cf. Marro v. K-III Commc’ns Corp.*, 943 F. Supp. 247, 254 (E.D.N.Y. 1996) (recognizing bond requirement may be waived in “unusual” circumstances). Moreover, “the district court must expressly address the issue of security before allowing any waiver and cannot ‘disregard the bond requirement altogether.’” *Pashby v. Delia*, 709 F.3d 307, 332 (4th Cir. 2013) (citing *Hoechst Diafoil*, 174 F.3d at 421).

In this Circuit, a district court may dispense with the security requirement only where the party restrained by the Injunction fails to “show[] that [it] will likely suffer harm absent the posting of a bond.” *Doctor’s Assocs., Inc. v. Stuart*, 85 F.3d 975, 985 (2d Cir. 1996); *see also Int’l Controls Corp. v. Vesco*, 490 F.2d 1334, 1356 (2d Cir. 1974) (“the district court may dispense with security where there has been no proof of likelihood of harm to the party enjoined”). That is not remotely the case here. As explained above, CoreRx *has* shown that it is likely to sustain significant harm if it is later determined that it was wrongfully enjoined, as will Azurity and the general public. (*See supra* Secs. I(B), I(D).)

Given the likelihood—indeed, certainty—of harm to CoreRx in the event of being forced to comply with an unwarranted Preliminary Injunction, the Court must order Bionpharma to post security in an amount sufficient to cover CoreRx’s anticipated damages in the event the Injunction is vacated on appeal.

CoreRx respectfully urges that a bond of at least [REDACTED] is appropriate on the facts here. As described more fully above (*see supra* Sec. I(B)), should the Preliminary Injunction not be stayed, CoreRx could be subject to liability to Azurity for patent infringement, exposing it to

potentially having to pay a damages award of up to [REDACTED]—or, at a very conservative estimate, [REDACTED]—as estimated by CoreRx’s expert economist. (*See supra* Sec. I(B); *see also* Opp. 20.) Accordingly, CoreRx respectfully requests that Bionpharma, in order to maintain the Injunction, be required to post security of at least [REDACTED].

CONCLUSION

For all the foregoing reasons, the Court should, on an expedited basis, (1) stay the Preliminary Injunction pending CoreRx’s appeal of the appropriateness thereof and (2) enter an order requiring Bionpharma to post security of at least [REDACTED] in order to maintain the Injunction.

Dated: New York, New York
February 7, 2022

Respectfully submitted,

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CERTIFICATION OF COMPLIANCE

I, Peter S. Russ, attorney for Defendant CoreRx, Inc., hereby certify that the foregoing Brief of Defendant CoreRx., Inc. in Opposition to Plaintiff Bionpharma Inc.'s Motion for Preliminary Injunction has a word count of 6,937, as counted by the word processing program used to prepare the brief, and that the brief complies with all formatting rules prescribed in the Individual Rules of Practice of Judge John G. Koeltl § 2(D).

Dated: New York, New York
February 7, 2022

By: /s/ Peter S. Russ
